Stent-graft versus open-surgical repair of the thoracic aorta: Mid-term results

David H. Stone, MD, David C. Brewster, MD, Christopher J. Kwolek, MD, Glenn M. LaMuraglia, MD, Mark F. Conrad, MD, Thomas K. Chung, MA, and **Richard P. Cambria, MD,** *Boston, Mass*

Objective: **Pivotal and comparative trial data are emerging for stent graft (SG) vs open repair of the thoracic aorta. We reviewed procedure-related perioperative morbidity, mortality, and mid-term outcomes in a contemporary series of patients treated with SG of the thoracic aorta. The data were compared with those of a patient cohort concurrently treated with open surgical repair confined to the descending aorta.**

Methods: **A review of patients undergoing SG procedures and open surgery of the thoracic aorta from January 1, 1996, to November 30, 2005, was performed from a prospectively compiled database. Study end points included perioperative complications, late survival, freedom from reinterventions, and graft-related complications. Multivariate methods were used to assess variables potentially associated with study end points; late outcomes were compared with actuarial methods.**

Results: **In 105 patients (mean age, 70 years; 66 male [62.9%]) SG repairs were done for 68 degenerative aneurysms (64.7%), 12 penetrating ulcers (11.4%), 15 pseudoaneurysms (14.3%), 9 traumatic tears (8.6%), and 1 acute dissection (0.9%). Mean follow-up was 22 months (range, 0 to 101 months). Eighty-nine (84.8%) SG patients were asymptomatic at presentation and underwent elective repair, whereas 16 (15.2%) presented with acute conditions and underwent urgent repair. Perioperative mortality was 7.6% (8/105), and actuarial survival at 48 months was 54% ± 7%. The perioperative mortality rate among SG patients treated for degenerative pathology was 10.4% (8/77). Seven (6.7%) of 105 patients experienced spinal cord ischemic complications, including 2 patients with transient paraparesis that resolved by the time of discharge. Reinterventions were performed in 10.5% of patients (11/105), with freedom from reintervention approaching 81% by 48 months. Over the same interval, 93 patients were treated with open-surgical repair for descending thoracic aneurysm (anastomosis cephalad to the celiac axis). Perioperative mortality in the open cohort was 15.1% (14/93; $P = .09$ vs SG repair), and the 48-month actuarial survival was 64% ± 6%. The incidence of spinal cord ischemic complications was 8.6% (8/93), including 4 patients with transient paraparesis ($P = .44$ vs SG repair). Nine patients (9.7%) required surgical reintervention during the follow-up period, with 48-month freedom from reintervention approaching 79% ($P = .73$ vs SG repair).**

Conclusions: **Operative mortality was halved with SG, with similar late survival for both cohorts. Reinterventions were required at a nearly identical rate for open repair and SG, and both groups experienced similar rates of spinal cord ischemic complications. (J Vasc Surg 2006;44:1188-97.)**

The incidence of degenerative thoracic aortic aneurysms has increased substantially in contemporary practice.[1,2] Such increase in prevalence will likely demand an increased need for thoracic aortic intervention.[2-4] Historically, conventional open surgery has been the mainstay of therapy; yet even in centers of excellence, operative mortality and paraplegia risks generally run in the 10% range.[5-8] Although initial reports of stent graft repair (SG) in the thoracic aorta created enthusiasm for a less invasive treatment alternative,[9,10] subsequent reports have since documented the safety and efficacy of SG of the thoracic aorta.[11-13] Pivotal and comparative (vs open repair) trial data are emerging for the spectrum of thoracic aortic pathology.[14-16] With the recent advent of an Food and Drug Administration–approved, commercially available device, the treatment paradigm for a variety of thoracic aortic pathologies has rapidly evolved toward stent-grafting strategies, although late results and level 1 evidence in the form of randomized clinical trials do not exist.[17-19]

Most reports detailing experience with TAA SG repair lack direct comparison with patients treated with open surgery; such data are largely limited to a single industry-sponsored pivotal trial.[11,14] With a study goal of providing such comparative data, we reviewed a contemporary concurrently treated series of patients managed with both SGs and open surgical repair for thoracic aortic pathology.

PATIENTS AND METHODS

During the interval from January 1996 to November 2005, 105 patients underwent SG repair of the thoracic aorta. Open surgical repair for degenerative (dissections excluded) descending thoracic aneurysms was done in 93 patients, of which 60% involved the entire descending aorta. Inclusion criteria included a distal aortic suture line cephalad to the celiac axis.

From the Division of Vascular and Endovascular Surgery and the Department of Surgery, Massachusetts General Hospital, Harvard Medical School.

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Reprint requests: Richard P. Cambria, MD, Division of Vascular and Endovascular Surgery, Massachusetts General Hospital, 15 Parkman St, WAC 458, Boston, MA 02114 (e-mail: rcambria@partners.org).

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Patients treated with SG repair received either commercially manufactured devices or custom-made SGs. The 20 custom-made devices consisted of an endoskeleton of self-expanding Gianturco Z stents (W. A. Cook, Inc, Bloomington, Ind) covered with an ironed woven Dacron graft (Cooley Veri-soft; Meadox Medicals, Inc, Oakland, NJ). These "first-generation" constructs were last used in 2004. All patients underwent perioperative evaluation with fine-cut (3-mm) computed tomography (CT) imaging of both the thoracic and abdominal aortic segments. Three-dimensional reconstructions were obtained to aid in device sizing for SG patients (Medical Metrx Solutions, West Lebanon, NH). Diagnostic angiography was also used selectively in the early stages of our experience.

Inclusion criteria generally involved 2-cm segments at proximal and distal fixation sites with vessel diameters not exceeding 37 mm in maximum diameter. More proximal fixation was achieved with associated exclusion of the left subclavian artery or left carotid artery.

Twenty-six patients (24%) were treated as part of the Medtronic-Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms (VALOR) trial, which included subgroups of both high-risk and compassionate device use patients (n = 16). Criteria for this group included high risk for open surgery (Society for Vascular Surgery (SVS) score of ≥3), or considered a nonsurgical candidate not associated with SVS scoring, or a patient with traumatic thoracic aortic injury who was otherwise stable, or a combination of these. TAG devices (W.L. Gore & Associates, Flagstaff, Ariz) were used to treat 22 patients (21%) in the context of phase II clinical trials, whereas 29 patients (28%) received Gore commercially available devices. Eight patients were treated with Cook Zenith Tx2 devices as part of the Zenith Tx2 thoracic endograft trial.

Specific clinical inclusion criteria for stent graft vs open-surgical repair were not applied over the study interval. In general, custom-made or compassionate use devices were applied in patients unfit for open repair; alternatively, such patients were entered into the VALOR high-risk arm, wherein enrollment ceased in 2002. Patients with anatomy amenable for SG repair were routinely offered participation in one of 4 industry-sponsored FDA–approved clinical trials with a variety of clinical exclusion criteria. Aneurysms were repaired in the context of symptoms, rapid enlargement, or approximate 6 cm size. Penetrating ulcers were repaired in context of an acute aortic syndrome, threatened rupture, or size > 6 cm.

Patient follow-up included clinical examination and CT imaging social security database follow-up was performed in each patient group. Comorbidities, including chronic obstructive pulmonary disease (COPD) with associated clinical impairment (forced expiratory volume in 1 second [FEV_1] <50% predicted), chronic renal insufficiency (serum creatinine >1.5 mg/dL), hypertension, diabetes mellitus, and tobacco use were assessed. Procedural outcome complications including cardiac (myocardial infarction), renal failure (+30% serum creatinine), pulmonary, and spinal cord ischemic complications were prospectively recorded. End points included periprocedural mortality (within 30 days or in-hospital death during the same admission), actuarial mid-term survival, freedom from reintervention, and endoleak.

Statistical analysis of comparative demographic and clinical variables, as well as study end points between the two cohorts, was performed with χ^2 testing Fisher's exact test, Student's t test, and Mann-Whitney tests. Survival analysis was performed by using Kaplan-Meier life tables with Mantel-Cox log-rank univariate analysis to identify differences between groups.

RESULTS

Patient characteristics. During the study interval, thoracic endografts were deployed in 105 patients; their mean age was 70 years, and 65 (61.9%) were men. Pathologies treated included 68 degenerative aneurysms (64.7%), 12 penetrating ulcers (11.4%), 15 pseudoaneurysms (14.3%), 9 traumatic tears (8.6%), and 1 acute dissection (0.9%). Devices used included 51 TAG (48.5%), 26 Talent (24.7%), 20 custom-made (19%), and 8 Zenith Tx2 (7.6%). By comparison, 93 patients (51 [54.8%] male; mean age, 71 years) underwent open-surgical repair of thoracic aortic aneurysms, as defined previously.

No difference was noted between groups regarding age, sex, hypertension, baseline renal function, COPD, or diabetes. A significant difference was noted in tobacco use among patients in the endograft cohort: 75.2% (79/105) vs 51.6% (48/93) in the open-surgical group ($P < .001$), as shown in the Table. Of significance, 27.6% (29/105) of stent graft patients were deemed unfit for conventional open-surgical repair secondary to significant comorbidities, including severe congestive heart failure, myocardial infarction, severe COPD (forced expiratory volume in 1 second 30%-50% predicted), or renal insufficiency (serum creatinine >2.2 mg/dL). Among patients with degenerative pathology, 29.9% (23/77) were deemed unfit for open surgery.

Perioperative mortality. Perioperative mortality was 7.6% (8/105) in the endograft cohort. By comparison, perioperative mortality in the open-surgical group was 15.1% (14/93; $P = .09$). Etiologies for perioperative mortality in the endograft group included myocardial infarction (n = 2), stroke (n = 2), small-bowel infarction (n = 2), and failed attempt at deployment with subsequent withdrawal of support (n = 1). There was one intraoperative death, which involved faulty device deployment with subsequent conversion to unsuccessful open repair. Among patients who underwent open-surgical repair, myocardial infarction (n = 5), stroke (n = 6), aortoenteric fistula (n = 1), sepsis (n = 1), and pancreatitis (n = 1) accounted for periprocedural mortality.

Subgroup analysis of perioperative mortality rates among SG patients with degenerative pathology (degenerative aneurysms and penetrating ulcers) was 10.4% compared with 15.1% in the open-surgical controls ($P = .37$). Furthermore, when ruptures were excluded from analysis,

Table I. Demographic and clinical features among patient cohorts.

Demographics	*Endo Cohort (n=77) Degenerative Cases*	*Endo Cohort (n=74) Degenerative excl. Rupt.*	*Open Cohort (n=93) Degenerative Cases*	*Open Cohort (n=83) Degenerative excl. Rupt.*
Age (years)	75.57 ± 7.76 [47-91]	75.61 ± 7.11 [47-89]	70.8 ± 9.8 (31-89)	70.2 ± 9.8 (31-89)
Gender	59.7% (46/77)	62.2% (46/74)	54.8% (51/93)	54.2% (45/83)
Smoking	81.8% (63/77)	83.8% (62/74)	51.6% (48/93)	51.8% (43/83)
HTN	90.9% (70/77)	90.5% (67/74)	84.9% (79/93)	84.3% (70/83)
Admit Creat.=>1.5	27.3% (21/77)	27.0% (20/74)	30.1% (28/93)	28.9% (24/83)
COPD	31.2% (24/77)	32.4% (24/74)	25.8% (24/93)	24.1% (20/83)
DM	13.0% (10/77)	13.5% (10/74)	7.5% (7/93)	7.2% (6/83)
Symptomatic	37.7% (29/77)	36.5% (27/74)	25.8% (24/93)	19.3% (16/83)

perioperative mortality rates were 8.1% in the SG group vs 9.6% in the open surgical cohort ($P = .74$).

Procedure-related data. Technical success of implantation, defined as device deployment at the intended segment/seal zone, was achieved in 100 (95.2%) of 105 patients. In three patients, the device could not be delivered to the intended fixation site because of either tortuosity or vascular injury. Faulty or incomplete device deployment occurred in two additional patients. A total of 185 devices were deployed in 105 subjects; 46.7% (n = 49) of patients received a single device, 30.5% (n = 32) received 2 devices, 21.9% (n = 23) received 3 device pieces, and 1% (n = 1) received 5 pieces at the initial procedure. The mean aortic length covered was 28.2 cm.

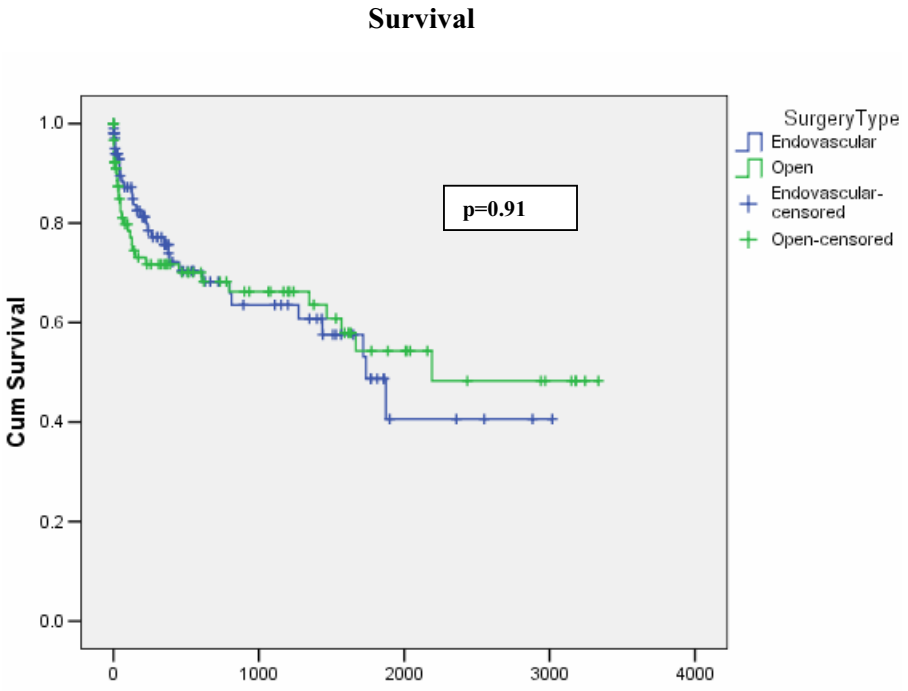
Arterial access was obtained via femoral cutdown in 76.2% (80/105) of patients, and 23.8% (n = 25) of patients required arterial conduit access for device introduction. Among this subgroup, 17.1% (n = 18) required iliac access via retroperitoneal cutdown, and 6.7% (n = 7) required an aortic arterial conduit. A total of 20% (21/105) of SGs were placed intentionally covering the left subclavian artery origin, and 11.4% (n = 12) underwent carotid subclavian bypass (57% of those with left subclavian coverage). Four patients (4%) required carotid-to-carotid bypass to enable SG seal proximal to the left common carotid origin. Management of the left subclavian artery varied by surgeon and clinical presentation. Ileofemoral access complications, defined as any injury incurred to the femoral or iliac arteries during the procedure, irrespective of access type, occurred in 17.2% (n = 14) of patients in the stent-graft cohort. These patients required lower midline laparotomy or retroperitoneal repair of the access vessels.

Open-surgical patients underwent open thoracotomy/thoracoabdominal incisions with clamp placement at or distal to the left subclavian artery and proximal to the celiac axis. Atrial-femoral bypass was used in 30 (32.3%) of the 93 patients; no cases were done with hypothermic circulatory arrest.

Spinal cord ischemia. The incidence of spinal cord ischemic complications (any degree of deficit) was 6.7% (7/105) in the SG group and 8.6% (8/93) in the open-surgery group ($P = .44$). The incidence of SCI complications in patients treated for degenerative pathology excluding ruptures was 10.4% in the SG cohort versus 7.2% in the open group ($P = 0.49$), paraplegia in the endograft cohort was 4.8% (5/105) and was 4.5% (4/93) in the open-surgical group ($P = .84$). Spinal cord–protective adjuncts were not routinely used in the endograft group but were implemented on a case-by-case basis, typically in patients with a history of abdominal aortic surgery or in anticipation of extensive descending aortic SG coverage.[21] In the open surgery cohort, 80.6% (75/93) had adjunctive use of cerebrospinal fluid drains, and 81.7% (76/93) had epidural cooling, as previously described,[21] vs close to 8% (8/105) in the SG group. Among the five cases of paraplegia in the endograft group, all were paraplegic with neurologic deficits noted immediately after surgery or on postoperative day 1. Thirty-three patients in the endograft group had previous AAA. Among the seven SG patients with SCI complications, 3 (42%) had previous AAA. Among paraplegic patients, two had previous AAA repair, and one of the patients with paraparesis had prior AAA repair (odds ratio, 2.04; 95% confidence interval, 0.64-6.5; $P = .23$). Among the paraplegic patients in the open-surgical group, all had spinal cord infarcts. Four patients in this group had transient lower extremity weakness. Two patients had early-onset left lower extremity weakness that resolved within 2 days. Two additional patients had bilateral lower extremity motor deficits that were resolved by discharge.

Stroke. Ten patients (9.5%) in the endovascular cohort sustained an intraoperative stroke and stroke occurred in 7 (7.5%) of the 93 open surgery patients ($P = .62$). Subgroup analysis of degenerative pathology, excluding rupture, revealed a 11.9% incidence of stroke in the SG group vs 6.0% in the open surgery group ($P = .2$). Among patients in the endograft cohort, 80% (8/10) had device manipulation across the arch with seal zones proximal to the left subclavian artery. One patient sustained a stroke secondary to device deployment proximal to the left carotid artery necessitating urgent carotid-carotid bypass. Postoperatively, the patient was found to have a large right middle cerebral artery distribution cerebrovascular accident (CVA) and subsequently died. A cerebrovascular accident occurred in a second patient after bare metal stent deployment across the left carotid artery that manifested as left hand weakness and in a third patient after attempted device deployment that was unsuccessful secondary to aortic tortuosity.

Length of stay. The mean intensive care unit length of stay among patients undergoing SG procedures was 3.65 days (range, 0-59 days) and was 9.26 days (range, 1-60



Months:	**0**	**12**	**24**	**36**	**48**
Open Repair					
At Risk:	93	45	34	25	18
S.E.	5	5	6	6	7
Stent Graft					
At Risk:	105	46	29	26	17
S.E.	5	6	6	7	8

Fig 1. Kaplan-Meier curve actuarial life-table analysis depicting intermediate (mid-term) survival between patients treated with thoracic stent grafts and open-surgical repair. *S.E.*, Standard error.

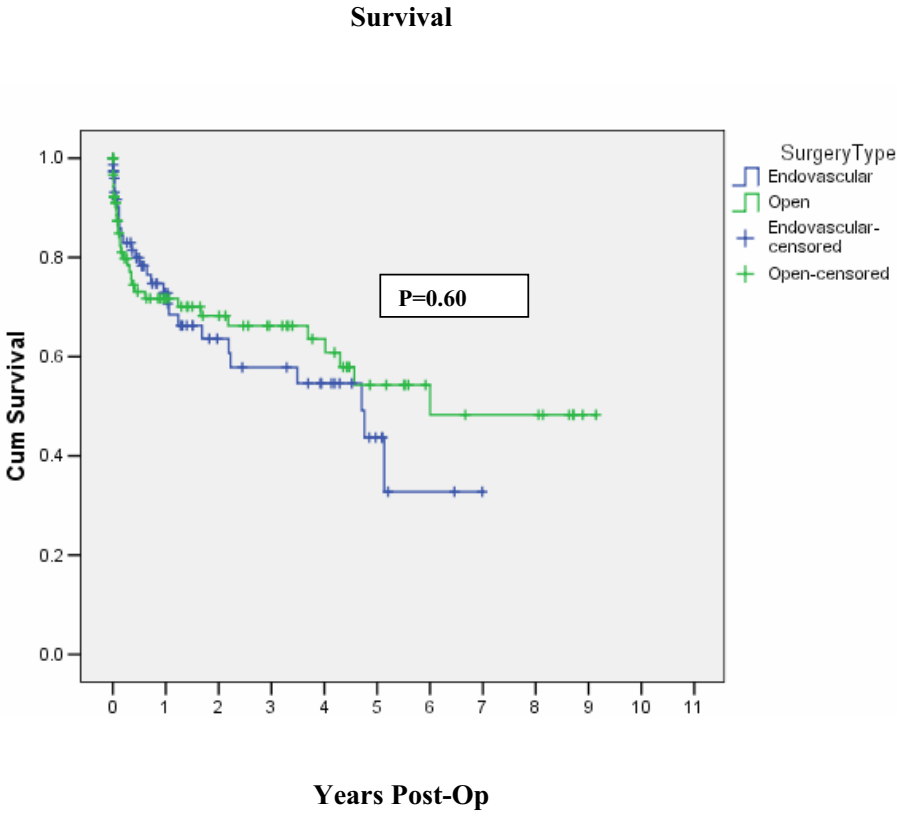
days) in the open-surgical group ($P < .001$). Mean total hospital length of stay was 11.0 days in the SG group vs 18.76 days in the open-surgical group ($P = .001$).

Late survival. Late survival for the SG and open surgical cohorts is depicted in Figs 1, 2 and 3. Kaplan-Meier 48-month survival was 54% ± 7% in the SG cohort vs 64% ± 6% in the open-surgical group ($P = .91$). Subgroup survival analysis for SG patients with degenerative aneurysms, excluding patients with traumatic tears, pseudoaneurysms, and acute dissection, revealed a 54% ± 7% 48-month survival vs 64% ± 6% in the open surgical group ($P = .60$). Furthermore, when the 30% of patients deemed unfit for open surgery were excluded, 48 month survival was 60 ± 8% in the SG group versus 64 ± 6% in the open group ($P = 0.47$).

Aneurysm-related mortality. The incidence of aneurysm-related death was 11.4% (12/105) among patients treated with SG versus 15.1% (14/93) in the open-surgical group ($P = 0.45$). Freedom from aneurysm-related mortality in the SG patients versus open-surgical patients was 85% ± 4% vs 82% ± 4%; ($P = 0.43$).

Endoleaks. Endoleaks at any time interval occurred in 14 patients (13.3%). These included six (42.9%) type I attachment site leaks, seven (50%) type II leaks, and one (7.1%) delayed type III endoleak.

Among patients with type I leaks, three asymptomatic patients were noted to have attachment site leaks with progressive sac enlargement on follow-up CT scan. All cases required reintervention. One patient initially thought to have a type II endoleak via retrograde perfusion from the



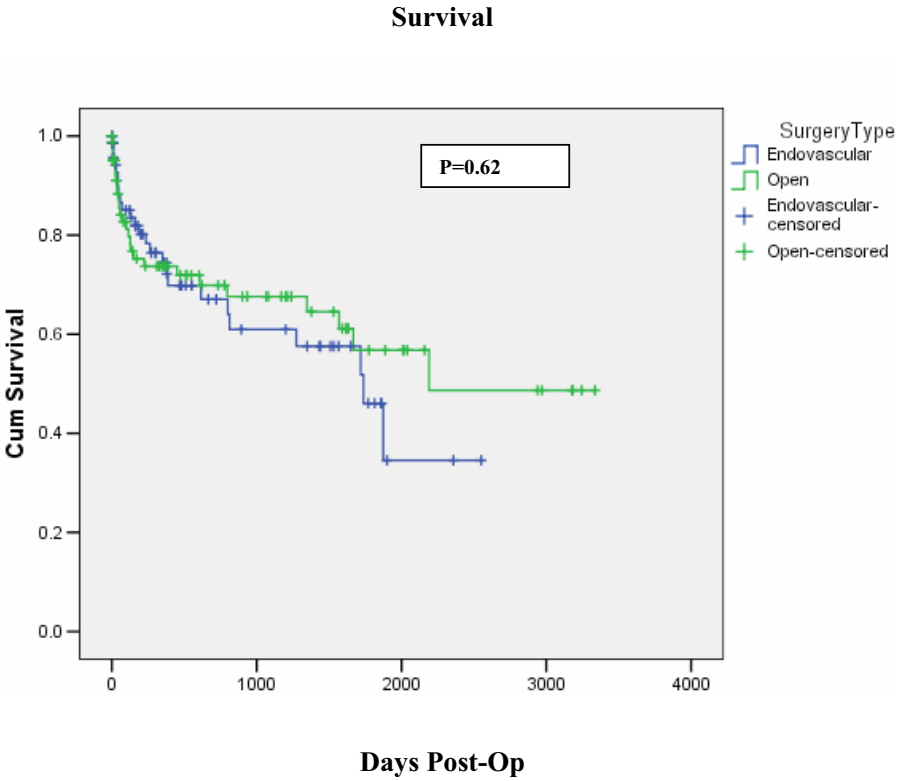
Months:	**0**	**12**	**24**	**36**	**48**
Open Repair					
At Risk:	93	46	36	29	23
S.E.	5	5	6	6	7
Stent Graft					
At Risk:	77	35	22	19	14
S.E.	6	7	7	7	9

Fig 2. Kaplan-Meier curve actuarial life-table analysis depicting intermediate (mid-term) survival between patients with degenerative aneurysms treated with thoracic stent grafts and open-surgical repair. *S.E.,* Standard error.

left subclavian artery underwent a left carotid subclavian bypass. Postprocedure angiography revealed a type I endoleak, which was then repaired with an additional device. One patient was noted to have a persistent distal attachment site leak treated with two Palmaz stents (Cordis, Miami Lakes, Fla). One patient was found to have proximal device collapse on serial imaging with reperfusion of a pseudoaneurysm and was repaired successfully with an additional device deployed across the proximal seal zone.

Among the seven patients noted to have type II endoleaks on follow-up imaging, three have completely resolved. The remaining four patients continue to be monitored and are asymptomatic. One patient presented 3 years postprocedure with evidence of a type III endoleak. She initially had required five device pieces to attain an adequate distal seal at the first procedure. Subsequently, the patient underwent reintervention with additional device deployment and resolution of the leak.

Freedom from reintervention. Reintervention is defined as all procedures performed on patients in either group referable to or as a consequence of the initial procedure performed. Reintervention for patients undergoing stent grafting was performed in 11 (10.5%) of 105 patients. These included a groin exploration for lymph leak, a carotid-subclavian bypass for a retrograde type II endoleak, and explantation of the device secondary to fungal infection.



Months:	**0**	**12**	**24**	**36**	**48**
Open Repair					
At Risk:	83	43	33	26	20
S.E.	5	6	6	6	7
Stent Graft					
At Risk:	74	34	22	19	14
S.E.	6	6	7	8	9

Fig 3. Kaplan-Meier curve actuarial life-table analysis comparing mid-term survival between SG patients and open-surgical controls, excluding cases of ruptured aneurysms. *S.E.,* Standard error.

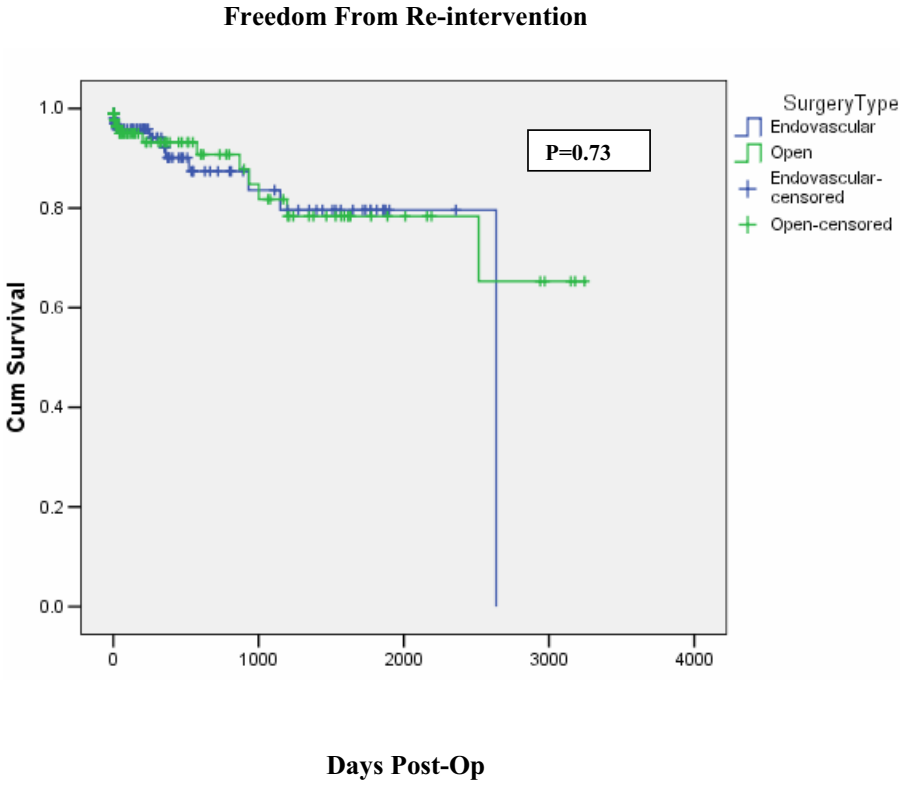
Additional reinterventions were performed for proximal device collapse, stent fracture/separation, an expanding aneurysm sac, and revision of a carotid-carotid bypass. Four patients (3.8%) required deployment of additional endovascular devices for endoleak.

By comparison, 9.7% (9/93) of patients who underwent open surgical repair required reintervention. Two patients required periprocedural ascending aorta and arch replacement secondary to retrograde aortic dissection from cross-clamp sites. Three patients warranted additional surgery for aneurysmal disease in contiguous aortic segments. One patient underwent abdominal exploration during the same hospitalization for a perforated viscus. Two patients required re-exploration for bleeding, and an additional patient required tracheostomy for ventilator dependence.

Kaplan-Meier actuarial freedom from reintervention at 48 months' follow-up was 80% ± 7% in the endograft group vs 78% ± 7% in the open-surgery group ($P = 0.73$; Fig 4). Subgroup analysis of freedom from reintervention in degenerative pathology cases only was 86% ± 5% in the endovascular group vs 82% ± 6% in the open-surgery group ($P = 0.9$). Freedom from reintervention among patients, excluding rupture cases, was 88% ± 5% in the SG group vs 83% ± 6% ($P = .89$).

DISCUSSION

Conventional surgical repair of descending thoracic aneurysms in centers of excellence is associated with mortality rates ranging from 4% to 9%, with paraplegia rates documented at roughly 4% to 14%.[5,11,22-24] Data from the



Months:	**0**	**12**	**24**	**36**	**48**
Open Repair					
At Risk:	93	45	34	25	18
S.E.	3	4	6	7	7
Stent Graft					
At Risk:	105	43	26	22	15
S.E.	3	4	5	7	7

Fig 4. Kaplan-Meier curve actuarial analysis depicting freedom from reintervention in patients treated with stent-graft repair and open surgery. *S.E.*, Standard error.

TAG investigators' pivotal trial comparing SG repair with open operation for descending thoracic aneurysms, and conducted in 16 major academic medical centers, indicate significantly diminished mortality (2.1% vs 11.7%) and SCI complications (3% vs 14%) for SG vs open repair.[11,14] Stent graft repair of the thoracic aorta for the treatment of the spectrum of aortic pathologies appears to offer a feasible and safe alternative compared with conventional repair.[10,11,17-19] Most reports of thoracic stent grafting offer promising results; however, these are generally retrospective single-center experiences.[1,25,26] The recent European Collaborators on Stent-Graft Techniques for AAA and Thoracic Aortic Aneurysm and Dissection Repair (EUROSTAR) and United Kingdom Thoracic Endograft registries, which comprise among the largest published experience with thoracic devices, suggest that SG repair is a safe and viable treatment strategy for patients with thoracic aortic pathology.[13] Most patients undergoing thoracic aortic stent grafting have been treated outside the confines of prospective clinical trials. To our knowledge, this report is among the first to offer both perspective and direct comparison with conventional surgical repair as well as midterm follow-up for SG treatment. Furthermore, unlike pivotal trial data, this study included a significant percentage of patients treated with SGs who were not open surgical candidates and perhaps better reflects patients typically encountered in contemporary practice.

The periprocedural mortality rate of 7.6% in this report among patients treated with SG is consistent with other studies, which often include patients treated in desperate

clinical circumstances and those unfit for open surgery, or both.[13,27,28] Despite borderline statistical significance, operative mortality in our study was halved with SG vs open repair; these data are further impressive because nearly 30% of SG patients were not open surgery candidates. The TAG investigators' pivotal trial data of 2.1% operative mortality clearly reflect the stringent inclusion criteria and elective nature of such cases. With respect to open operation, the 15.1% (10% excluding ruptures) reported herein is quite similar to the W. L. Gore pivotal trial data of 11.7% mortality in the open surgery control group with intact aneurysms.[11,14] Recently reported data from high-volume centers are similar (8% mortality) and likely reflect a "best case scenario" for open operation.[24] Similar to the experience with endovascular stent grafting for AAA,[30] the accumulating evidence indicates a clear advantage for SG repair with respect to operative mortality.

Actuarial survival at 48 months in our endograft cohort was 54% ± 7%, and the corresponding figure for open surgery patients was 64% ± 6% ($P = 0.91$; Fig 1). These data are similar to the TAG investigator's actuarial 2-year survival of 78% in patients treated with thoracic SGs vs 76% in patients treated with open surgery ($P = 0.48$). Likewise, EUROSTAR and United Kingdom Thoracic Endograft registries report a 1-year actuarial survival of 80% among patients treated with thoracic SGs for degenerative aneurysms.[13] In another report documenting mid-term follow-up survival, Demers et al[12] report a 5-year survival of 49% ± 5% among patients treated with thoracic SGs vs 78% ± 6% for open surgery patients, yet the authors appropriately emphasize that these data reflect the inclusion of patients who were deemed reasonable surgical candidates only.

Our experience with a 95.2% technical success at implantation rate likely reflects improved second-generation devices.[11,13,27] Currently, anatomic restrictions such as severe thoracic aortic tortuosity, short landing and sealing zones, and extensive mural thrombus have been limiting factors, although a seemingly infinite variety of debranching and bypass procedures can be applied to extend either the proximal or distal sealing zones.[30,31] An important consideration in the deployment of thoracic SGs remains arterial access. Current SG device parameters and accompanying sheath diameters frequently warrant alternative arterial access using either iliac or aortic conduits; for example 23.8% of the SG cohort in this series required alternative arterial access. Gore phase II data document a 15% rate of alternative access required for device deployment.[11] White et al[32] noted a 27% access site complication rate. The rate of access site complications for SG patients in this report was about 15.2% (n = 16), and this led to a fatality in one instance. The prevalence of such procedure-associated complications related to thoracic aortic stent grafting highlights the importance of performing such procedures in an operating room environment. Specific strategies to both avoid and deal with access-related issues are reviewed elsewhere.[33]

In any discussion of the relative merits of stent grafting and open surgery of the thoracic aorta, consideration of secondary interventions or reinterventions figures prominently. Specifically, Demers et al[12] document a rate for actuarial freedom from reintervention of 77% ± 5% at 5 years, similar to our findings of 80% ± 7% at 48 months. Our data challenge the tacit assumption that reinterventions in the open surgery patients would a priori be less than in SG patients, although this depends on how such interventions are defined. For example, we consider it legitimate to include tracheostomy as a reintervention, even though not specific to the surgical graft. Freedom from reintervention in our SG group approached 80% ± 7% vs 78% ± 7% in the open surgery group at 48 months follow-up ($P = 0.73$). In most series, similar to our findings, endoleak accounts for most reinterventions in the patients treated with a SG.[11,12] By comparison, reintervention for patients undergoing open surgery often reflects persistent or recurrent disease in contiguous aortic segments. Reintervention rates in Gore phase II clinical trial reports document seven reinterventions (5%) in the stent-graft cohort after 2 years of follow-up, whereas no patients in the open surgical cohort required reintervention at 2 years.[11] Reintervention rates will also reflect clinical decision making in treating patients with TAAs in regard to the extent of resection. We previously reported that 20% of our TAA cohort had residual aneurysm disease after resection and 25% of our TAA patients had prior aortic resections. As many as 50% of patients undergoing TAA repair will have synchronous or metachronous aneurysm disease.[5,34] The increased availability of SG treatment options further permits the opportunity to stage resection of diffuse disease, with reliance on SG reintervention to treat more proximal aortic segments. As this staged hybrid open and endovascular treatment paradigm becomes more widespread, it may cloud reported reintervention data associated with specific treatments. There remains a paucity of late follow-up reintervention data among SG series. It is likely that the number of reinterventions among thoracic SG patients will increase as longer follow-up data become available.

Accumulating evidence suggests that the risk of SCI complications is significantly decreased in SG groups compared with patients undergoing open repair.[11,33] Indeed, in the first available comparative trial of SG vs open repair for descending thoracic aneurysms, there was a significant reduction in repair with SG (2.9% vs 13.8% incidence; $P = 0.003$).[11,13] The data reported in this study are quite different, with an essentially equivalent SCI rate (6.7% vs. 8.6%; $P = 0.44$). Previously, we reported an overall SCI rate of 11% in a series of 337 patients undergoing thoracoabdominal aneurysm repair, recognizing that these patients are at higher risk than patients with isolated aneurysm disease of the descending thoracic aorta.[5,23] The relatively high paraplegia rate in the pivotal trial open-surgical control cohort may reflect a broader cross section of surgeons with different backgrounds and the inconsistent or absent application of spinal cord–protective adjuncts (although 78% were repaired with distal aortic perfusion techniques).

The modest rate of paraplegia in our cohort likely reflects a consistent (since 1993) application of spinal cord–protective adjuncts that have been previously documented to decrease the incidence of SCI.[5,20]

It has been suggested that the incidence of spinal cord complications may correlate with long aortic segment exclusion with SG devices and previous AAA repair.[21,36] Despite the concern for extensive intercostal arterial exclusion during SG repair, the reported incidence of neurologic complications remains low, from 2.9% to 12%.[13,21,35] Pivotal trial data cite a 4.7% incidence of paraplegia in patients treated previously for AAA, and a 2% incidence among patients without prior aortic replacement.[11,14] The data reported in this study indicate no correlation with prior AAA repair, however the statistical power of these findings is unreliable owing to small patient numbers. It is our posture to incorporate spinal cord–protective adjuncts in patients in whom long segment aortic coverage is anticipated or patients with previous abdominal aortic resection. We manage these patients in an intensive care unit setting with arterial catheters and cerebrospinal fluid drains for at least 24 to 48 hours postprocedure, specifically to avoid perioperative hypotension. Our open surgical patients are routinely treated with spinal cord–protective adjuncts.

Stroke risk during SG repair remains an important consideration, particularly in cases where arch fixation is required. The incidence of stroke among SG patients in this series was 9.5% (10/105). Among these patients, eight (80%) had proximal device fixation in the transverse arch. Gore phase II trial reports document 5 patients among 140 who experienced periprocedural cerebrovascular accident,[11] 4 of whom had a planned bypass procedure secondary to proximal aneurysmal disease that required device fixation in the arch. We strongly consider the quality of the arch fixation sites as important in clinical decision-making. Debranching operative strategies are likely safer than fixation in diseased arch segments.

CONCLUSION

Our SG cohort had half the periprocedural mortality of open surgery patients, despite overall higher risk. Mid-term survival appears to be equivalent between the two groups. Arterial access remains an important consideration, as does scrupulous follow-up. Although long-term durability remains undefined, this may be less of a consideration in older patients with degenerative conditions and finite survival. Because SG repair offers lower periprocedural risk, it is our current practice to perform SG repair when anatomically feasible.

AUTHOR CONTRIBUTIONS

Conception and design: DHS, RPC
Analysis and interpretation: DHS, TKC, RPC
Data collection: DHS, MFC, TKC
Writing the article: DHS, DCB, RPC
Critical revision of the article: DHS, DCB, CJK, RPC
Final approval of the article: DHS, DCB, CJK, GML, MFC, TKC, RPC
Statistical analysis: DHS, TKC, RPC
Overall responsibility: DHS

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